

UNITED STATES OF AMERICA
Before the
SECURITIES AND EXCHANGE COMMISSION

SECURITIES ACT OF 1933
Release No. 10417 / September 28, 2017

SECURITIES EXCHANGE ACT OF 1934
Release No. 81742 / September 28, 2017

ADMINISTRATIVE PROCEEDING
File No. 3-18228

<p>In the Matter of</p> <p style="text-align:center">ALERE INC.,</p> <p>Respondent.</p>
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ORDER INSTITUTING CEASE-AND-DESIST PROCEEDINGS, PURSUANT TO SECTION 8A OF THE SECURITIES ACT OF 1933 AND SECTION 21C OF THE SECURITIES EXCHANGE ACT OF 1934, MAKING FINDINGS, AND IMPOSING A CEASE-AND-DESIST ORDER

I.

The Securities and Exchange Commission (“Commission”) deems it appropriate and in the public interest that public administrative and cease-and-desist proceedings be, and hereby are, instituted pursuant to Section 8A of the Securities Act of 1933 (“Securities Act”) and Section 21C of the Securities Exchange Act of 1934 (“Exchange Act”) against Alere Inc. (“Respondent”).

II.

In anticipation of the institution of these proceedings, Respondent has submitted an Offer of Settlement (the “Offer”) which the Commission has determined to accept. Solely for the purpose of these proceedings and any other proceedings brought by or on behalf of the Commission, or to which the Commission is a party, and without admitting or denying the findings herein, except as to the Commission’s jurisdiction over it and the subject matter of these proceedings, which are admitted, Respondent consents to the entry of this Order Instituting Cease-and-Desist Proceedings, Pursuant to Section 8A of the Securities Act of 1933 and Section 21C of the Securities Exchange Act of 1934, Making Findings, and Imposing a Cease-and-Desist Order (“Order”), as set forth below.

III.

On the basis of this Order and Respondent's Offer, the Commission finds¹ that:

Summary

1. Alere is a Massachusetts-based public company, traded on the New York Stock Exchange, which manufactures and sells diagnostic tests for infectious disease, cardiometabolic disease and toxicology. Alere maintains operations and sells its products around the world. Between 2011 and 2016, Alere engaged in the improper premature recognition of revenue in its financial statements filed with the Commission. And, between 2011 and 2013, Alere's subsidiary in Colombia improperly characterized payments to a Colombian government official in Alere's books and records. Alere's subsidiary in India also failed to properly record certain payments made by a distributor in its books and records. Alere further failed to devise and maintain a sufficient system of internal accounting controls. As a result, Alere violated Sections 10(b), 13(a), 13(b)(2)(A), and 13(b)(2)(B) of the Exchange Act and Rules 10b-5, 12b-20, 13a-1, 13a-11, and 13a-13 thereunder, and Section 17(a) of the Securities Act.

2. Since May 2015, Alere has at three different times revised or restated its financial statements that had appeared in the company's periodic filings with the Commission. In May 2015, Alere restated its 2014 Form 10-K due to incorrect tax accounting. In August 2016, Alere filed its 2015 Form 10-K, which revised the revenue and associated entries in its financial statements for prior periods due to incorrect reporting of revenue. In June 2017, Alere filed its 2016 Form 10-K, which restated its revenue and associated entries for prior periods due to newly discovered improper reporting of revenue. In total, Alere has restated its financial statements for fiscal years 2013, 2014, and 2015 and for the following fiscal quarters: Q3 2014, Q1-Q3 2015, and Q1-Q3 2016.

3. **Revenue Recognition Problems:** From 2011 to 2016, Alere misstated its revenue in its financial statements filed with the Commission. These revenue misstatements resulted from (a) intentional early reporting of revenue by Alere's South Korean subsidiary, Standard Diagnostics, and (b) improper revenue recognition practices by Alere at subsidiaries located, among other locations, in South Korea, Israel, South Africa, Ireland, and China. The improper revenue recognition practices primarily related to the timing of when Alere could have recognized the revenue. As a result, Alere's revision and restatement of its revenue over the five-year period, shifted to a later reporting period in total over \$260 million in revenue from the quarter in which it was originally recognized. The revenue involved in "early sales" and other practices described below was eventually recognizable and collected, just not in the quarter in which it was recorded.

4. **Recording of Offers and Payments to Foreign Officials:** Between 2011 and 2013, Alere's foreign subsidiaries located in Colombia and India indirectly made improper offers

¹ The findings herein are made pursuant to Respondent's Offer of Settlement and are not binding on any other person or entity in this or any other proceeding.

and payments to foreign government officials for the purpose of making sales of its products. Profits from the sales associated with the improper offers and payments totaled approximately \$3.3 million.

Respondent

5. **Alere Inc.** is a Delaware corporation with its principal place of business in Waltham, MA. It is a manufacturer of medical diagnostic testing equipment. Alere's common stock is registered pursuant to Section 12(b) of the Exchange Act and trades on the New York Stock Exchange under the symbol "ALR."

Other Relevant Entities

6. **Alere Colombia S.A.** is a wholly-owned subsidiary of Alere formerly known as BioSystems, S.A. ("BioSystems"). Alere Colombia sells Alere's global products into the Colombian market. Alere Colombia is located in Bogota, Colombia. Biosystems was an independent distributor of Alere products until acquired by Alere.

7. **Standard Diagnostics, Inc.** ("SD") is a wholly-owned subsidiary of Alere. Its main products test for diseases such as Malaria, Dengue, HIV, and Syphilis. Standard Diagnostic's principal office is located in Giheung-gu, South Korea. Prior to 2010, Standard Diagnostics was an independent and publicly-traded company listed in South Korea. Alere acquired, through a tender offer, a majority share of its stock in 2010.

8. **Alere Medical Private Ltd.** ("Alere India") is a wholly-owned subsidiary of Alere. Alere India sells Alere's global products into the Indian market. Alere India's principal office is located in Gurgaon, India.

9. The **VP of SD Sales**, a resident and citizen of Korea, served as the head of SD's sales and marketing departments from 2011 until 2016. In 2013, he was also given the title of Vice President of Commercial Operations Africa. During the entire time he was a management-level employee working from an office in South Korea. Alere intended to terminate the VP of SD Sales in 2015 based on conduct not related to the matters discussed herein, but postponed the termination to cooperate with ongoing government investigations. The VP of SD Sales resigned in 2016.

10. The **SD Finance Director**, a resident and citizen of Korea, served as the head of SD's finance department from 2011 until 2017. He was removed from his position following an internal investigation in 2017 and subsequently resigned.

Facts

11. During the 2000s and early 2010s, Alere grew quickly, in part because it acquired a number of foreign companies. Alere's corporate finance group required all these newly acquired companies to adopt Alere's Revenue Recognition Policy.

12. Alere's Revenue Recognition Policy established standards and procedures to ensure that Alere recognized revenue in compliance with management's objectives and U.S.

generally accepted accounting principles (“GAAP”). Among other things, the policy stated that revenue should not be recognized until four basic criteria have been met: “(1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the fee is fixed and determinable; and (4) collection is reasonably assured.” More specifically, the policy stated that Alere recognizes revenue upon title transfer of the products to third-party customers.

13. Alere’s corporate finance group delegated revenue recognition decision-making authority to Alere’s subsidiaries. These subsidiaries entered their revenue information into local books and records, which were consolidated into Alere’s own books and records and used to create the financial statements that it filed with the Commission.

Intentional False Reporting of Revenue at Alere’s South Korean-Subsidiary, SD

14. In February 2010, Alere acquired a majority interest in SD. Beginning with fiscal year 2010, SD’s financials were consolidated into Alere’s financial statements, which were filed in Alere’s Form 10-K.

15. Beginning no later than 2011, the VP of SD Sales initiated a scheme to inflate SD’s revenue numbers at or near the end of reporting periods. The VP of SD Sales and other SD employees wanted to accelerate revenue in order to meet African region sales quarterly and annual revenue targets. The scheme involved recognizing revenue before delivery of the product had occurred in violation of Alere’s Revenue Recognition Policy and in contravention of GAAP. The practice came to be known amongst SD employees as “early sales.”

16. “Early sales” were generally conducted in one of two ways:

- a. In the first scenario, the product remained undelivered in SD’s warehouse at the end of a quarter. SD employees then intentionally created false delivery documents or falsified shipping documents to support a delivery date before the end of a quarter. This falsified documentation was used to recognize the sale of product days or weeks earlier than its actual delivery.
- b. In the second scenario, immediately before the end of a quarter, SD would direct a shipping agent to pick up product and store it in the shipping agent’s warehouse until the customer requested delivery. SD employees used the pick-up receipts from the shipping agent as proof of delivery to a customer. This documentation was improperly used to recognize the sale of product days or weeks earlier than its actual delivery.

17. The size of the transactions for which revenue was improperly recognized ranged from as small as \$25,000 to greater than \$2 million.

18. To execute the scheme, the VP of SD Sales involved personnel from SD’s sales, marketing, customer service, and warehouse departments.

19. Over time, the number of sales transactions improperly recognized early each quarter grew, peaking in 2015. In the fourth quarter of 2015, SD's fraudulent "early sales" comprised approximately 29% of all the revenue SD reported that quarter. This inflated revenue was incorporated in financial statements filed with Alere's 2015 Form 10-K.

20. Initially, the scheme did not directly involve employees within SD's finance department. But by the end of 2015, at least two individuals in SD's finance department, the SD Finance Director and an SD Finance Manager, were aware of and complicit in "early sales."

21. During 2016, in response to issues with revenue recognition in China and Africa, Alere's management conducted an internal assessment of revenue recognition practices throughout its subsidiaries. During the assessment, the SD Finance Director and the SD Finance Manager intentionally concealed the "early sales" scheme from those conducting the assessment and Alere's independent auditors.

22. In fact, SD continued to prematurely recognize revenue during Alere's ongoing assessment by improperly recognizing revenue from unconsummated sales on the last day of Q2 and Q3 2016. SD's improper revenue recognition continued through Q4 2016.

23. As a result of the conduct described above, Alere violated Section 10(b) of the Securities Exchange Act, Rule 10b-5 thereunder, which prohibit fraudulent conduct in connection with the purchase or sale of securities, and Section 17(a) of the Securities Act which prohibits fraudulent conduct in the offer and sale of securities. This conduct also contributed to Alere's violations of Sections 13(a), 13(b)(2)(A), and 13(b)(2)(B) of the Exchange Act and Rules 12b-20, 13a-1, 13a-11, and 13a-13 thereunder, which require every issuer of a security registered pursuant to Section 12 of the Exchange Act to file with the Commission information, documents, and annual and quarterly reports as the Commission may require, and mandate that periodic reports contain such further material information as may be necessary to make the required statements not misleading.

Failure to Conform Revenue Reporting to GAAP by Alere from 2013-2016

Chinese "Bill and Hold" Transactions

24. From Q4 2012 through Q1 2016, employees at an Alere subsidiary located in China recognized revenue from the sale of product that remained undelivered at the subsidiary's warehouses. The practice was called "postponement of delivery." While customers agreed not to take delivery and submitted a "Declaration of Postponement" form to the subsidiary, the arrangement did not permit the recognition of revenue under applicable Bill & Hold guidance under GAAP. From 2013 to 2016, the subsidiary entered into more than 3,800 "postponement of delivery" transactions associated with more than \$28 million in revenue that was recognized in an earlier quarter than permissible under GAAP.

African Contingent Arrangements, Bill-and-Hold Transactions, and Revenue Cut-off Issues

25. From at least 2013 through 2015, employees of Alere's Africa commercial team entered into sales arrangements for which revenue was improperly recognized. Sales included contingent arrangements,² bill and hold transactions,³ and sales where product was stored at a third-party's warehouse. In addition, revenue from certain sales of Alere product to be used in Africa was improperly recognized due to cut-off issues and improper execution of or changes to shipping terms.

26. Alere's Africa commercial team included employees from Alere's Israeli, South African, and Irish subsidiaries and employees from SD. In general, commercial and finance personnel lacked a sufficient understanding of how such arrangements and shipping terms affected when Alere could recognize revenue under U.S. GAAP.

27. These sales arrangements and issues led to Alere recognizing revenue of approximately \$24 million in an earlier quarter than permissible under GAAP.

African Distributor Sales Agreements

28. From at least 2011 through 2015, employees of Alere's Africa commercial team made sales to distributors operating in Africa pursuant to distributor sales agreements. Many of the agreements with African distributors executed by Alere's Israeli and South African subsidiaries contained a provision, a "Retention of Title" clause, that stated Alere retained title to the product until it was paid in full by the distributor.⁴ As written, the provision precluded Alere from recognizing revenue under GAAP until Alere received payment for the product from the distributor. Finance personnel, however, either failed to review the Retention of Title clause in the agreements or were unaware of its implication for revenue recognition.

29. Typically, Alere's African distributor customers had at least 30 days to pay for products. Lacking the resources and understanding of GAAP, Alere's subsidiaries, recognized revenue upon delivery, often immediately before or at the end of a quarter, even though without payment this was not proper given the presence of the Retention of Title clause.

30. As a result, Alere recognized more than \$86 million in revenue from sales to African distributors in an earlier quarter than permissible under GAAP.

² Contingent arrangements do not become fixed or determinable until the contingency resolves, and thus, revenue may not be recognized until that time.

⁴ The distribution agreements generally included language stating that the distributor was holding the product for Alere and the product needed to be stored separately and labeled as Alere's product and that Alere maintained the right to enter the distributors' premises and remove its product. As such, these distributor arrangements were broad and therefore extended beyond the retention of title exemption contemplated in Staff Accounting Bulletin No. 104.

Other Revenue Recognition Issues

31. In addition, from at least 2013 through 2015, Alere experienced wide-spread month or quarter end revenue cut-off issues at subsidiaries located around the world, including in Argentina, Australia, Brazil, China, Colombia, Japan, the United States, and Europe. The various subsidiaries independently used similar improper quarter end cut-off procedures for revenue.

32. As a result of the improper revenue recognition cut-off practices, Alere recognized approximately \$97 million in revenue from non-African customers in an earlier quarter than permissible under GAAP.

33. The conduct at Alere's subsidiaries described above contributed to Alere's violations of 13(a), 13(b)(2)(A), and 13(b)(2)(B) of the Exchange Act and Rules 12b-20, 13a-1, 13a-11, and 13a-13 thereunder, and Sections 17(a)(2) and (3) of the Securities Act.

Improper Revenue Recognition Led to Required Restatements of Commission Filings and Revisions of Financial Statements and Assessments of the Effectiveness of Internal Control over Financial Reporting

34. To correct the inaccurate revenue reporting summarized above, Alere revised and restated its financial statements.

35. On February 26, 2016, Alere filed a Form 12b-25 with the Commission announcing a delay in the filing of its Form 10-K for the year ended December 31, 2015 due to management's "analysis of certain aspects of revenue recognition in Africa and China and any potential implications on our evaluation of internal control over financial reporting for the year ended December 31, 2015."

36. Management completed its assessment of revenue recognition and filed with the Commission Form 10-K for 2015 on August 8, 2016. Alere reported:

Based on our review, we determined that, in 2013 and 2014 and the first three quarters of 2015, we had incorrectly recorded certain revenue transactions for such periods. Specifically, the errors in the application of U.S. GAAP rules regarding the timing of revenue recognition primarily relate to: (i) transactions, principally in Africa, in which we recognized revenue when the product shipped to the distributor, but we contractually retained title in the products until the distributor paid for the products in full or the distributor was not obligated to pay us until the products were sold through to the end-user; (ii) "bill and hold" transactions, principally in China, which did not meet the criteria for revenue recognition under U.S. GAAP; and (iii) other transactions, in which we recognized revenue prior to full satisfaction of all contractual criteria for title and risk of loss passing to the customer.

37. Alere concluded that it had several material weaknesses in internal control over financial reporting related to revenue recognition:

a. We did not maintain a sufficient complement of resources at our subsidiaries with appropriate knowledge, experience and training to ensure proper application of US GAAP in determining revenue recognition.

b. We also did not maintain effective controls over information and communications as it relates to revenue recognition at our subsidiaries. Specifically, we did not implement and reinforce an adequate process for internally communicating nonstandard terms and conditions between our subsidiaries' commercial operations and finance groups and between our subsidiaries' finance groups and our corporate accounting group.

c. We did not design effective controls over the review of terms of purchase orders and customer contracts, including amendments to contracts, to ensure proper application of US GAAP in determining revenue recognition.

d. We did not design effective controls to ensure that revenue would not be recognized until title and risk of loss had passed to our customers.

38. On March 1, 2017, Alere filed another Form 12b-25 with the Commission, announcing a delay in filing its Form 10-K for 2016 because the Company was "reviewing certain aspects of revenue recognition at its Korean ... location[]." Specifically, Alere disclosed "inappropriate conduct at the Company's subsidiary in South Korea, Standard Diagnostics, Inc."

39. On April 17, Alere filed Form 8-K with the Commission, to announce that its Audit Committee had concluded that the Company's previously filed financial statements for the years ended December 31, 2013, 2014 and 2015, and the first three quarters of 2016, should not be relied upon.

40. On June 5, 2017, following an internal investigation into the South Korean conduct, Alere filed its Form 10-K with the Commission for 2016. The investigation found that previously filed financial statements included errors involving the timing of revenue recognition caused by, "...among other things, misrepresentation and/or fabrication of documents used to validate revenue recognition...."

41. Alere's restated financial statements in the 2016 Form 10-K also establish that Alere's press releases announcing its quarterly and annual financial results filed with the Commission as exhibits to its Form 8-Ks were also misstated.

42. The table below illustrates the cumulative impact of the out-of-period accounting errors on net revenue and net income (loss) recorded by Alere in its August 2016 revision and the June 2017 restatement for the periods 2013, 2014 and the first three quarters of 2015 which were subject to the August 2016 revision.⁵

⁵ The "as reported" amounts in the table below are the net revenues and net income (loss) amounts reported by Alere prior to the August 8, 2016 revision.

Impact on Previously Issued Financial Statements Filed Prior to the August 2016 Revision (in \$000s)					
	2013	2014	Q1 2015	Q2 2015	Q3 2015
Net Revenue (As Reported)	\$ 2,616,364	\$ 2,588,704	\$ 608,153	\$ 629,156	\$ 602,044
Restatement and Revision Adjustments	(9,009)	(11,703)	1,753	(5,182)	2,555
Net Revenue (As Restated and Revised)	2,607,355	2,577,001	609,906	623,974	604,599
	2013	2014	Q1 2015	Q2 2015	Q3 2015
Net Income (Loss) (As Reported)	\$ (71,733)	\$ (37,710)	\$ 209,228	\$ 20,263	\$ 5,501
Restatement and Revision Adjustments	(1,805)	4,587	885	(5,765)	(6,969)
Net Income (Loss) (As Restated and Revised)	(73,538)	(33,123)	210,113	14,498	(1,468)

43. The table below illustrates the cumulative impact of the out-of-period accounting errors on net revenue and net income (loss) recorded by Alere in its June 2017 restatement for the periods Q4 2015 through Q3 2016.⁶

Impact on Previously Issued Financial Statements Filed on and After August 2016 Revision (in \$000s)					
	Q4 2015	2015	Q1 2016	Q2 2016	Q3 2016
Net Revenue (As Reported)	\$ 623,285	\$ 2,463,316	\$ 578,209	\$ 611,088	\$ 582,354
Restatement Adjustments	(6,149)	(7,701)	8,731	(784)	(72)
Net Revenue (As Restated)	617,136	2,455,615	586,940	610,304	582,282
	Q4 2015	2015	Q1 2016	Q2 2016	Q3 2016
Net Income (Loss) (As Reported)	\$ (16,059)	\$ 206,757	\$ (9,977)	\$ (34,891)	\$ 22,027
Restatement Adjustments	(3,018)	(2,692)	4,005	2,084	(6,364)
Net Income (Loss) (As Restated)	(19,077)	204,065	(5,972)	(32,807)	15,663

44. Alere reported in its Form 10-K for 2016 that the four material weaknesses cited in the 2015 10-K remained in place as of December 31, 2016 and Alere added a fifth material weakness disclosure:

We did not maintain an effective control environment at [SD]. Specifically, certain employees at SD engaged in inappropriate conduct, which was facilitated by an inadequate segregation of duties, including (a) colluding with subordinates and certain third parties to circumvent controls and fabricate documents related to revenue recognition and other matters, some of which were provided to finance management and our external auditors and (b) overriding controls related to the observation of physical inventories. In addition, other employees, including certain members of SD finance management responsible for other controls at the subsidiary, were aware of the override of controls but did not report this conduct as required by our policies and procedures.

Alere Also Misstated Its Financial Statements Due to Tax Accounting Errors

45. By 2014, Alere stopped acquiring companies and instead began to divest itself of various subsidiaries and business segments. In October 2014, Alere sold two subsidiaries, Accountable Care Solutions, LLC and Wellogic ME FZ – LLC. In January 2015, Alere sold the

⁶ The “as reported” amounts in the table below are the net revenues and net income (loss) amounts reported by Alere in the August 8, 2016 revision for Q4 2015 and the full-year 2015 and subsequent Form 10-Qs for the three quarters in 2016.

remaining portion of its health management business. These sales affected Alere's accounting for its income taxes including income tax expense or benefit and associated assets and liabilities.

46. On February 10, 2015, before it finished its tax accounting for Fiscal Year 2014, Alere released its unaudited financial results for the quarter ended December 31, 2014. It announced a net loss of \$165 million.

47. Alere's external tax consultants advised the head of Alere's tax department that Alere was incorrectly accounting for Alere's divestiture of part of its health management business. The head of the tax department disagreed and decided not to follow the advice of the external tax consultants.

48. Alere intended to file its Form 10-K on March 3, 2015, but its external auditor questioned the tax accounting for the sale of the health management business. The external auditor took the same position as Alere's external tax consultant had. As a result, instead of filing its Form 10-K with the Commission, Alere filed for a 15-day extension and began recalculating its tax provision and associated assets and liabilities.

49. Two days later, on March 5, 2015, Alere filed its 10-K. Correcting the tax error contained in the previously disclosed financial results caused an increase in Alere's reported net income of over \$175 million for the year ended December 31, 2014 which caused the previously reported net loss to swing to profit of approximately \$10 million.

50. While closing the financial statements for the first quarter of 2015 in April 2015, Alere discovered that its previous calculations for the tax impact of the divestiture were incorrect. After further analysis, Alere concluded that it had also incorrectly accounted for the tax impact of the divestiture of the other subsidiaries it sold in October 2014. As a result of these errors (and other out-of-period errors predominately related to tax matters), on May 28, 2015, Alere filed an amended Form 10-K for the year ended December 31, 2014 which restated the previously reported net income of approximately \$10 million to a net loss of over \$37 million.

51. The conduct described above contributed to Alere's violations of 13(a), 13(b)(2)(A), and 13(b)(2)(B) of the Exchange Act and Rules 12b-20, 13a-1, 13a-11, and 13a-13 thereunder.

Tax Accounting Errors Led to Required Restatements of Financial Statements and Assessments of Effectiveness of Internal Control over Financial Reporting

52. On March 5, 2015, Alere filed with the Commission its Form 10-K for the 2014 fiscal year. That Form 10-K disclosed a material weakness in Alere's Internal Control over Financial Reporting. The accounting error was corrected in the 2014 financial statements, and the material weakness as of December 31, 2014 was disclosed as follows:

We did not design effective controls to assess the accounting for deferred tax assets which become recognizable as a result of dispositions.

53. On May 28, 2015, Alere filed with the Commission its Form 10-K/A, amending and restating the Form 10-K it filed in March 2015. Alere concurrently filed Form 10-Q/A for the third quarter of 2014. The financial statements for the remaining 2014 quarters and prior years presented in the filings were revised, but not restated. The accounting errors leading to the May 2015 restatement principally related to the areas covered by the previously disclosed material weakness, but also incorporated other out-of-period errors involving tax and non-tax areas. The following table illustrates the impact to Alere’s previously reported annual net income (in \$000s):

Period	Previously Reported Net Income (Loss)	Adjustment	Net Income (Loss) As Restated / Revised
FY 2014	\$ 9,948	\$ (47,658)	\$ (37,710)
FY 2013	(70,278)	(1,455)	(71,733)
FY 2012	(77,907)	(310)	(78,217)

54. In connection with the May 28, 2015 Form 10-K/A, Alere revised its previously disclosed material weakness as of December 31, 2014:

We did not design effective controls to assess the accounting for deferred taxes related to dispositions.

55. On November 9, 2015, Alere filed with the Commission its Form 10-Q for the third quarter ended September 30, 2015. In this filing, Alere disclosed that it had discovered and corrected certain out-of-period errors related to 2014 in Q3 2015 associated with accounting for U.S. taxes on foreign earnings. In the Form 10-Q for Q3 2015, Alere expanded its disclosure of the material weakness which existed at December 31, 2014 to:

We did not maintain a sufficient complement of resources with adequate experience and expertise in accounting for income taxes, as a result of which our accounting controls did not operate at a level of precision to identify errors in the calculation of tax balances resulting from dispositions and U.S. taxes on foreign earnings.

56. On November 13, 2015, Alere filed another Form 10-K/A for 2014 to restate its previously filed financial statements. The Form 10-K/A incorporated the expanded material weakness disclosure described in the Form 10-Q filed five days before.

**Alere Recorded Improper Payments
from BioSystems to a Government Official in Colombia**

57. During 2007 and 2008, Alere purchased a private Colombian distributor of Alere products called BioSystems, S.A., ultimately renaming it Alere Colombia in 2016. In conjunction with the acquisition, Alere installed Biosystems’ former primary shareholder and owner as Biosystems’ General Manager (the “Colombia GM”).

58. Biosystems' customers included a set of entities known as an Entidad Promotora de Salud, or EPS, which provided health insurance services for their members. These entities were created by Colombian law as part of the Colombian government's efforts to provide universal health benefits to its citizens. Under this system, EPSs were responsible for organizing and guaranteeing the provision of health services for their enrolled participants and managing their participants' health risks. Among other things, EPSs contracted for health services on behalf of their participants through a network of public, private, and their own health service providers. EPSs were both private and government controlled.

59. From at least 2006, Biosystems sold products to an EPS that operated as a private entity (the "Customer EPS"). Biosystems' contact at the Customer EPS was a management level employee ("the "Customer EPS Manager") responsible for, among other things, recommending and approving products – including Biosystems' products – for the Customer EPS to purchase and provide to its enrolled participants. The Colombia GM oversaw the Customer EPS account and dealt directly with the Customer EPS Manager.

60. During 2011 through 2013, due to allegations of mismanagement at the Customer EPS, the Government of Colombia, acting through the Ministry of Health, took control and direction of the Customer EPS. During this time, the Customer EPS was an instrumentality of the Government of Colombia and its employees were officials of the Government of Colombia. In 2013, the Ministry of Health began dissolving the Customer EPS and transferring its members to another EPS.

61. From 2007 through at least 2012, Biosystems, at the direction of the Colombia GM, made improper payments totaling approximately \$275,000 to the Customer EPS Manager in order to obtain and retain business from the Customer EPS. The payments began at least six months before Alere acquired Biosystems. Biosystems disguised these improper payments as payments for purported consulting services from the Customer EPS Manager's husband, sister-in-law, and friend. In fact, none of the recipients of these improper payments performed legitimate consulting services for Biosystems sufficient to justify the amount of payments received.

62. From 2011 through 2013, Biosystems sold approximately \$7.6 million of products to the Customer EPS. During this time, the Customer EPS Manager continued in her position at the Customer EPS and remained responsible for recommending Biosystems' products to the Customer EPS. From 2011 through 2013, Biosystems earned approximately \$3.18 million in profits from the approximate \$7.6 million in sales to the Customer EPS. In 2013, the Colombia GM hired the Customer EPS Manager to work at Biosystems.

63. In 2015, Alere's corporate management began an internal investigation into consulting payments at Biosystems and discovered the improper payments. Shortly thereafter, the Customer EPS Manager resigned from Biosystems. The Colombia GM had previously resigned from Biosystems in January 2015.

64. The improper payments to the Customer EPS Manager were recorded as legitimate consulting expenses in Biosystems' books and records. Biosystems' books and

records were consolidated into Alere's books and records thereby causing Alere's books and records to be inaccurate. Alere also failed to devise and maintain an adequate system of accounting controls sufficient to prevent and detect the improper payments that occurred over several years.

65. Through the conduct described above, Alere violated Sections 13(b)(2)(A) and 13(b)(2)(B) of the Exchange Act through the inaccurate recording of the payments to the Customer EPS's relations on its books and records, and its failure to devise or maintain internal accounting controls sufficient to provide reasonable assurances that its funds would not be used to make improper payments in contravention of Alere's policies.

**Alere India Failed to Maintain Internal Controls
Against Improper Payments to Government Officials**

66. In 2011, an India-based subsidiary of Alere, Alere Medical Pvt. Ltd. ("Alere India"), acting through an India-based distributor ("India Distributor"), won a contract to provide malaria testing kits to a local governmental entity for a national disease control program.

67. In early 2012, the India Distributor wrote a letter to Alere India's then-Vice President of Marketing and Sales about the tender. The India Distributor noted that it had met with officials of the local governmental entity who had informed them that if the local governmental officials were paid a four percent commission, they would increase the orders under the tender from 200,000 to 1,000,000 testing kits. Alere India's Vice President of Marketing and Sales approved the four percent commission and the India Distributor proceeded to incorporate the increased commission amount into the prices for the test kits. Alere India failed to record the additional commission in its books and records.

68. In August 2012, the India Distributor requested from Alere India a credit memo for the commission it had paid the local government officials in connection with the initial 200,000 test kits it had provided to the local governmental entity. Around the same time, the India Distributor paid Alere India the amounts owed for the 200,000 test kits, but deducted the commission paid to the local government officials from the total payment amount. The India Distributor noted the reasons for the deduction on an invoice accompanying the payment.

69. In December 2012, the new management at Alere India discovered the unpaid credit memo associated with the 200,000 test kits. Alere's corporate management initiated an internal investigation, and it directed Alere India to refuse to issue the requested credit memo. Alere India requested and received reimbursement from the India Distributor for increased commission the India Distributor had withheld on that order. Alere, however, retained the approximate \$150,000 in profits that it obtained from the increased contract.

70. Through the conduct described above, Alere violated Sections 13(b)(2)(A) and 13(b)(2)(B) of the Exchange Act through the inaccurate recording of the commissions paid by Alere India on its books and records, and its failure to devise or maintain internal accounting controls sufficient to provide reasonable assurances that its funds would not be used to make improper payments in contravention of Alere's policies.

Alere Offered Securities

71. During the relevant period, Alere issued shares through a number of employee share purchase programs offered to employees. Also during the relevant period, Alere issued debt securities, including, on June 24, 2015, Alere completed an offering of \$425 million of 6.375% senior subordinated notes due in 2023. Alere also issued senior notes on December 11, 2012 and May 24, 2013.

Violations

72. Section 10(b) of the Exchange Act and Rule 10b-5 thereunder prohibit fraudulent conduct in connection with the purchase and sale of a security. As a result of the conduct described above related to early sales at SD, Alere violated Section 10(b) of the Exchange Act and Rule 10b-5 thereunder.

73. Section 17(a) of the Securities Act prohibits fraudulent conduct in the offer and sale of securities. As a result of the conduct described above, Alere violated Section 17(a) of the Securities Act.

74. Section 13(a) of the Exchange Act requires issuers of securities registered pursuant to Section 12 of the Exchange Act to file periodic and other reports with the Commission. With exceptions not applicable here, Rules 13a-1, 13a-11, and 13a-13 of the Exchange Act require each issuer to file annual, current, and quarterly reports respectively on the appropriate forms and within the period specific on the form. Rule 12b-20 further requires that the required reports contain such further material information, if any, as may be necessary to make the required statements, in light of the circumstances under which they are made not misleading. As a result of the conduct described above, Alere violated Section 13(a) of the Exchange Act and Rules 12b-20, 13a-1, 13a-11, and 13a-13 thereunder.

75. Section 13(b)(2)(A) of the Exchange Act requires issuers of securities registered pursuant to Section 12 of the Exchange Act to make and keep books, records and accounts, which, in reasonable detail, accurately and fairly reflect their transactions and dispositions of their assets. As a result of the conduct described above, Alere violated Section 13(b)(2)(A) of the Exchange Act.

76. Section 13(b)(2)(B) of the Exchange Act requires issuers of securities registered pursuant to Section 12 of the Exchange Act to, among other things, devise and maintain a system of internal accounting controls sufficient to provide reasonable assurances that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles and that transactions are executed in accordance with management's general or specific authorization. As a result of the conduct described above, Alere violated Section 13(b)(2)(B) of the Exchange Act.

IV.

In view of the foregoing, the Commission deems it appropriate to impose the sanctions agreed to in Respondent Alere's Offer.

Accordingly, pursuant to Section 8A of the Securities Act and Section 21C of the Exchange Act, it is hereby ORDERED that:

A. Respondent Alere shall cease and desist from committing or causing any violations and any future violations of Sections 10(b), 13(a), 13(b)(2)(A), and 13(b)(2)(B) of the Exchange Act and Rules 10b-5, 12b-20, 13a-1, 13a-11, and 13a-13thereunder, and Section 17(a) of the Securities Act.

B. Respondent shall, within 14 days of the entry of this Order, pay a civil money penalty of \$9,200,000, disgorgement of \$3,328,689, and prejudgment interest of \$495,196 to the Securities and Exchange Commission for transfer to the general fund of the United States Treasury, subject to Exchange Act Section 21F(g)(3). If timely payment is not made, additional interest shall accrue pursuant to SEC Rule of Practice 600 and 31 U.S.C. §3717.

Payment must be made in one of the following ways:

- (1) Respondent may transmit payment electronically to the Commission, which will provide detailed ACH transfer/Fedwire instructions upon request;
- (2) Respondent may make direct payment from a bank account via Pay.gov through the SEC website at <http://www.sec.gov/about/offices/ofm.htm>; or
- (3) Respondent may pay by certified check, bank cashier's check, or United States postal money order, made payable to the Securities and Exchange Commission and hand-delivered or mailed to:

Enterprise Services Center
Accounts Receivable Branch
HQ Bldg., Room 181, AMZ-341
6500 South MacArthur Boulevard
Oklahoma City, OK 73169

Payments by check or money order must be accompanied by a cover letter identifying Alere, Inc. as a Respondent in these proceedings, and the file number of these proceedings; a copy of the cover letter and check or money order must be sent to Associate Director John T.Dugan, Division of Enforcement, Securities and Exchange Commission, Boston Regional Office, 33 Arch Street, 24th Floor, Boston, MA 02110.

C. Amounts ordered to be paid as civil money penalties pursuant to this Order shall be treated as penalties paid to the government for all purposes, including all tax purposes. To preserve the deterrent effect of the civil penalty, Respondent agrees that in any Related Investor Action, it shall not argue that it is entitled to, nor shall it benefit by, offset or reduction of any award of compensatory damages by the amount of any part of Respondent's payment of a civil penalty in this action ("Penalty Offset"). If the court in any Related Investor Action grants such

a Penalty Offset, Respondent agrees that it shall, within 30 days after entry of a final order granting the Penalty Offset, notify the Commission's counsel in this action and pay the amount of the Penalty Offset to the Securities and Exchange Commission. Such a payment shall not be deemed an additional civil penalty and shall not be deemed to change the amount of the civil penalty imposed in this proceeding. For purposes of this paragraph, a "Related Investor Action" means a private damages action brought against Respondent by or on behalf of one or more investors based on substantially the same facts as alleged in the Order instituted by the Commission in this proceeding.

By the Commission.

Brent J. Fields
Secretary